Invitation from Nagoya Protocol Secretariat

A. Decision NP-1/10: the need for and modalities of a global multilateral benefit-sharing mechanism

Paragraph 1 of decision NP-1/10 invites Parties, other Governments, international organizations, indigenous and local communities, and relevant stakeholders to submit to the Executive Secretary views on:

(i) Situations which may support the need for a global multilateral benefit-sharing mechanism that are not covered under the bilateral approach;

(ii) Possible modalities for a global multilateral benefit-sharing mechanism as well as information regarding the implications of different scenarios on these modalities; and

(iii) The areas requiring further consideration, as identified in paragraph 23 of the report of the Expert Meeting on Article 10 of the Nagoya Protocol.

Such views may include, where available, reflections on any experiences gained working towards the implementation of the Nagoya Protocol.

The areas for further examination as identified in paragraph 23 of the report of the Expert Meeting on Article 10 of the Nagoya Protocol are provided in the annex to this notification (*see below*).

Parties to the Nagoya Protocol, other Governments, international organizations, indigenous and local communities and relevant stakeholders are invited to submit views on the above matter as soon as possible and no later than **30 September 2015**.

The views submitted are to be synthesized for consideration by an expert meeting, which is tentatively scheduled for 1 to 3 February 2016, in Montreal, Canada. More details on the meeting, including the invitation for nominations, will be circulated by notification in due course.

USG Proposed Response

Article 10 instructs Parties to consider the need for a Global Multilateral Benefit Sharing Mechanism (GMBSM) in specific circumstances. We have considered the issue extensively and see no need for such a GMBSM at this time. Cooperation between the parties concerned, including under Article 11, could adequately address many of the concerns raised in paragraph 23 of report of the Expert Meeting on Article 10 of the Nagoya Protocol, to the extent those concerns fall within the scope and mandate of the Convention on Biological Diversity and the Nagoya Protocol.

Further, it is important to keep in mind that any possible identified need for a GMBSM must pass the test of whether it fits the specific circumstances described in Article 10, i.e., *transboundary situations* or where *it is not possible to grant or obtain prior informed consent.* The United States does not consider many of the concerns identified in paragraph 23 to fit the specific circumstances described in Article 10, and therefore are not appropriate situations that

would warrant the development of a GMBSM. We have provided additional comments regarding each of the concerns identified in paragraph 23 below.

U.S. government specific comments on Paragraph 23 (indicated in bullets below each point).

The areas for further examination as identified in paragraph 23 of the report of the Expert Meeting on Article 10 of the Nagoya Protocol (document UNEP/CBD/ICNP/3/5) are as follows:

(a) Whether or not there is a need for a GMBSM;

- We have considered the issue extensively and see no need for a GMBSM at this time. The circumstances contemplated in Article 10 – involving transboundary situations or where it is not possible to grant or obtain prior informed consent – can be adequately addressed through the implementation of other provisions of the Nagoya Protocol and other existing instruments.

(b) Whether there is sufficient experience with implementation of the Protocol to determine whether such a need exists;

- We note that the Nagoya Protocol has only recently entered into force, and most Parties are still working to establish appropriate legislative, administrative or policy measures to implement the Protocol. We recommend first monitoring the development of measures designed to implement the Protocol and assessing the results of these efforts before further considering whether the need for or modalities of a GMBSM exist.

(c) Whether the utilization of genetic resources without PIC would entail benefit-sharing obligations that could be met through a GMBSM;

- The Nagoya Protocol is already designed to address, including through its agreed provisions on compliance, cases where PIC is required and the genetic resources have nevertheless been accessed and utilized without PIC. A GMBSM would not add value in this regard.

- The consideration of a GMBSM under Article 10 is limited to a narrower question regarding PIC, i.e., where it is not *possible* to grant or obtain PIC.

    - It is not possible to grant or obtain PIC for genetic resources from areas beyond national jurisdiction, but those are beyond the scope of the Nagoya Protocol (and in any event are being considered elsewhere, in the "biodiversity beyond national jurisdiction" preparatory committee set up by the UN General Assembly).

    - It is also impossible to obtain PIC for genetic resources already accessed/utilized; this, too, is beyond the scope of the Nagoya Protocol, and also as a practical and legal matter infeasible to address in a GMBSM. (For example, for a long time records were not required regarding where genetic resources came from, so there is no way to know the source, conditions under which the genetic resources were accessed; or if there was even a foreign source at all; and existing contracts regarding the use of already transferred genetic resources cannot generally be modified.)

- Also, note that PIC is not always required, and the "utilization of genetic resources without PIC" does not necessarily create a problem if no PIC was required.

(d) Whether a Party's decision not to require PIC (e.g. under Art. 6(1)) or to waive PIC (e.g. under Art. 8) can constitute situations for which it is not possible to grant or obtain PIC in the context of Article 10;

- No, access and benefit-sharing under the Convention is predicated upon the exercise of sovereign rights within a Party's own jurisdiction. If a providing country chooses not to require PIC or benefit-sharing for accessing its genetic resources, that is its sovereign decision, with which requirements under a GMBSM would conflict.

(e) Whether benefit-sharing requirements are waived when a Party has decided not to require PIC or has waived PIC;

- Benefit-sharing requirements are imposed by providers, which may or may not be national authorities. Thus, even in a country like the United States without a general national PIC requirement, providers of genetic resources may transfer them on mutually agreed terms that require benefit-sharing. Those benefit-sharing requirements, which may exist in the form of a contract, are not waived just because there is not also a national PIC requirement.
- As to situations where the benefit-sharing requirements in question are imposed at the national level (as where the national government is itself the provider of the genetic resources), the question is whether national law could ever require benefit-sharing upon utilization even without a PIC requirement. Ensuring adequate notice and fairness for people who access genetic resources are important considerations in that regard, as is the need to ensure that benefit-sharing requirements are nevertheless on mutually agreed terms. At the same time, full efforts should be made to ensure that a predictable environment is created that serves to encourage and foster discovery and innovation.

(f) Whether there is no requirement for benefit-sharing when mutually agreed terms are not required or have not been established;

- The Protocol requires benefit-sharing to be on mutually agreed terms. A provider can always choose not to require benefit-sharing; it is not unlawful for a provider to transfer genetic resources with no conditions attached. Indeed, in some sectors this is routine. The United States does not consider it appropriate for others (through a GMBSM or otherwise) to undermine the decision of a sovereign power under the Protocol that has decided not to require PIC or, in the case of genetic resources provided by the Party itself, MAT. In other circumstances, where national law requires PIC and MAT, and MAT does not exist (for example because one government agency indicated that no MAT is required and a court subsequently finds that they were the wrong authority), it would be inconsistent with the treaty to retrospectively require benefit sharing on unilaterally imposed terms.

(g) Whether the absence of ABS legislation or regulatory requirements in a Party due to lack of capacity or lack of governance means that PIC for access to genetic resources is not required and

there is no obligation to share benefits. In the context of Article 10, whether such instances would constitute situations for which it is not possible to grant or obtain PIC;

- Establishing appropriate ABS legislation or regulatory requirements is a responsibility of a Party as outlined in Article 6 and the lack thereof should not constitute situations for which it is not possible to grant or obtain PIC in the context of Article 10.
- Further, where the intent of the providing country with regards to ABS legislation or regulatory requirements cannot be determined, the central question may be whether others can determine the intent of a sovereign power under the Protocol. We do not see how it is appropriate for outside governments to decide such issues on behalf of the providing Party through any GMBSM.

(h) Whether the absence of measures in a Party to implement Article 7 means that PIC for access to traditional knowledge associated with genetic resources is not required and there is no obligation to share benefits. In the context of Article 10, whether such instances would constitute situations for which it is not possible to grant or obtain PIC;

- Establishing measures, as appropriate, as outlined in Article 6 is for a Party to determine in accordance with its domestic law, and the lack of such measures should not constitute situations for which it is not possible to grant or obtain PIC in the context of Article 10.

(i) Whether a genetic resource that is found in more than one Party constitutes a transboundary situation in the language of Article 10 (even if it is possible to identify the source of the genetic resource) or whether the bilateral approach should be applied if a genetic resource is found in more than one Party and it is possible to identify the source of the genetic resource. In the latter case, whether the bilateral approach or a GMBSM could be fair and equitable;

- Article 6 provides that access to genetic resources shall be subject to the PIC of the Party providing such resources, unless otherwise determined by that Party. Article 11 of the Nagoya Protocol states that when the same genetic resources are found *in situ* in the territory of more than one Party, the Parties shall endeavor to cooperate, as appropriate, with the involvement of the ILCs concerned, where applicable, with a view to implementing the Protocol. This article adequately addresses transboundary situations. It is up for the sovereign countries and providers involved to decide, in cooperation where appropriate, whether and how to require PIC and MAT with respect to their genetic resources. PIC is not required with each and every Party having the genetic resource.

(j) Whether traditional knowledge associated with a genetic resource that is found in more than one Party constitutes a transboundary situation in the language of Article 10 (even if it is possible to identify the source of the genetic resource) or whether the bilateral approach should be applied if traditional knowledge associated with a genetic resource is found in more than one Party and it is possible to identify the source of the genetic resource. In the latter case, whether the bilateral approach or a GMBSM could be fair and equitable;

- There is no need for Article 10 to address this situation, as it is adequately contemplated in Article 11.
    - To the extent the genetic resource is what is located in more than one Party (as opposed to the traditional knowledge associated with the genetic resource), see the response to (i), above.

- Article 11 adequately addresses situations where traditional knowledge is shared by one or more ILCs in several Parties: "Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol."

(k) Whether Article 11 is sufficient to respond to transboundary situations;

- Yes (see discussion above).

(l) Whether a GMBSM should address the sharing of benefits arising from the utilization of:

(i) Genetic resources in *ex situ* collections in relation to transboundary situations or for which it is not possible to grant or obtain PIC;

(ii) Genetic resources in *ex situ* collections used for purposes for which PIC was not granted and for which it is not possible to grant or obtain PIC;

For l (i) and l (ii):

- A GMBSM would not be needed to manage genetic resources obtained from *ex situ* collections. To the extent benefit-sharing requirements within the scope of the Nagoya Protocol apply to such collections, the bilateral approach is adequate.

(iii) Genetic resources in areas beyond national jurisdiction or whether this issue falls within the competence of the United Nations General Assembly;

- Such genetic resources fall outside the scope of the Nagoya Protocol (including article 10). Moreover, the issue of marine genetic resources in areas beyond national jurisdiction is under active consideration by the preparatory committee set up by the UN General Assembly. It is not appropriate or productive for this forum to engage on this issue and duplicate or prejudge the work of the preparatory committee on this matter.

(iv) Genetic resources in the Antarctic Treaty area;

- Such genetic resources fall outside the scope of the Nagoya Protocol (including article 10). Moreover, the issue of genetic resources in the Antarctic Treaty area is being considered by the Antarctic Treaty Consultative Parties, who in Resolution 6(2013) of the Antarctic Treaty Consultative Meeting "[r]eaffirm[ed] that the Antarctic Treaty System is the appropriate framework for managing the collection of biological material in the Antarctic Treaty area and for considering its use". It is not appropriate or productive for this forum to engage on this issue and duplicate or prejudge the work of the Antarctic Treaty Consultative Parties on this matter.

(v) Traditional knowledge associated with genetic resources that is publicly available and where the holders of such traditional knowledge cannot be identified or for which it is not possible to grant or obtain PIC.

- Traditional knowledge associated with genetic resources that is public information should not be included under any GMBSM, regardless of whether any holders of the traditional knowledge can be identified.